



SPL Pathways

Pathways for successful creation & submission of SPL R4 Documents
Scenarios eBooks Series

Requesting a New or Submitting an Already Assigned NDC Labeler Code in SPL Format

Version 1.0

Purpose: This SPL R4 training Pathways eBook is to be utilized as a guide if you are requesting a new NDC Labeler Code or submitting an already assigned NDC Labeler code in SPL format.

Create an NDC Labeler Code SPL document following the instructions in SPL training eBook # 3 “Creating and Submitting NDC Labeler Code SPL Documents” which is accessible via this web page: <http://spl-work-group.wikispaces.com/SPL+eBooks+-+Graphic+Guides>

A. Requesting a new NDC Labeler Code

1. Submit a valid NDC Labeler Code Request SPL document (**without** an NDC labeler code)
2. Check Gateway Inbox or Other Documents folder for second acknowledgment (error message)
3. If no errors are received within 48 hours (business days), await assignment of NDC labeler code
4. Receive notification of newly assigned NDC labeler code via an e-mail from FDA
5. Update NDC Labeler Code Request SPL document with newly assigned NDC labeler code
6. Do NOT change the setID for this file
7. Submit updated NDC Labeler Code SPL document with newly assigned NDC labeler code
8. Check Gateway Inbox or Other Documents folder for second acknowledgment (error message)

B. Submitting an already assigned NDC Labeler Code

1. Submit a valid NDC Labeler Code Request SPL document (with an **already assigned** NDC labeler code)
2. Check Gateway Inbox or Other Documents folder for second acknowledgment (error message)
3. If no errors are received within 48 hours (business days) then your submission passed validation.